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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/202,104 04/30/99 VAN LEENGOED

L 3890US

EXAMINER

HM12/0508

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PRASAD, S

ART UNIT PAPER NUMBER

1646

DATE MAILED:

05/08/01

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/202,104

Applicant(s)

Van Leengoed et al.

Examiner

Sarada C Prasad

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-70 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

**(1) Detailed Action**

1. This application is a 371 of PCT/NL97/00345. For applications filed under 371, PCT Rules for lack of unity apply.
2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept. Under PCT Rule 13.1 the following combinations of claims of different categories are permissible and restriction to one of the following combinations is required.

The Groups are as follows:

Group I: Claims 1, 4-12, 15-17, 20-24 are drawn to peptides exhibiting antagonistic activity directed against IL-6, and their methods of use.

Group II: Claims 13-15 are drawn to an antibody against peptides exhibiting antagonistic activity directed against IL-6.

Group III: Claims 18-19 are drawn to a diagnostic assay comprising a peptide exhibiting antagonistic activity directed against IL-6.

Group IV: Claim(s) 2, 25-37, 39-41, 44-48 are drawn to peptides exhibiting antagonistic activity directed against the  $\alpha$  or  $\beta$  chain of the IL-6 receptor and methods of using them.

Group V: Claim(s) 37-39 are drawn to an antibody against peptides exhibiting antagonistic activity directed against the  $\alpha$  or  $\beta$  chain of the IL-6 receptor.

Group VI: Claim(s) 42-43 are drawn to a diagnostic assay comprising peptides exhibiting antagonistic activity directed against the  $\alpha$  or  $\beta$  chain of the IL-6 receptor.

Group VII: Claims 3, 49-58, 61-63, 65-70 are drawn to peptides exhibiting antagonistic or agonistic IL-6 activity and methods of using them.

Group VIII: Claims 59-61, drawn to antibodies against peptides exhibiting antagonistic or agonistic IL-6 activity.

Group IX: Claims 64-65, drawn to a diagnostic assay comprising peptides exhibiting antagonistic or agonistic IL-6 activity.

These inventions listed as Groups I-IX do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical features of Groups I, IV, and VII are considered to be the peptides exhibiting (i) antagonistic activity directed against IL-6 and methods of using them; or (ii) antagonistic activity directed against the  $\alpha$  or  $\beta$  chain of the IL-6 receptor and methods of using them; or (iii) antagonistic or agonistic IL-6 activity and methods of using them respectively.

Accordingly, Groups I, IV, and VII are not so linked by the same or corresponding technical feature as to form a single general inventive concept.

Furthermore, Groups II-III also contain claims not so linked to form a single general inventive concept under PCT Rule 13.1. For example: methods of using peptides to make antibodies in Group II are not considered to possess the same technical feature as methods of diagnostic assays as in group III and therefore these groups exhibit lack unity of invention. In a similar manner, groups V-VI and VIII-IX corresponding to groups I and IV respectively, lack the same technical feature in that the peptides (groups IV and VII), antibodies to peptides (groups V and VIII), and diagnostic methods using peptides or antibodies (groups VI and IX) are not so linked to form a single general inventive concept.

The inventions I-IX do not meet the requirements for Unity of invention for the following reasons. The inventions do not share the special technical feature which defines a contribution which each of the inventions makes over the prior art. Several of the peptides are known to be of interest as diagnostic markers for in vitro use, or for therapy for in vivo use, or for antibody

preparation. Thus the same peptides have patentably distinct uses which are not related and hence a search for one would not reveal art for another.

Furthermore, Applicants are required to specify one specific polynucleotide or polypeptide sequence for examination. This requirement is made in view of 1192 O.G. 68 Notice (November 19, 1996), as the examination of more than one sequence in one application would result in an undue burden on the PTO. Based up on this requirement, no matter which invention is elected Applicants are required to elect a single peptide of specific SEQ ID NO for examination purposes.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1646

*Advisory Information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarada C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday - Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyley, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sarada Prasad, Ph.D.  
Examiner Art Unit 1646  
May 7th, 2001

*Prema Mertz*  
PREMA MERTZ  
PRIMARY EXAMINER